

AMENDMENT

Amendments to the Claims:

Please change the claim status identifier markings in claims 53-55, 62 and 98-100, and amend claim 56-58 and 97 so that the text of the amended claim reads as shown in the complete listing of claims below:

Claims 1-52. (Cancelled)

53. (~~Withdrawn~~ Original) A liquid-crystalline multimolecular aggregate comprising a plurality of amphiphilic molecules dispersed in an aqueous solution, said amphiphilic molecules comprising a hydrophilic component having at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus of said hydrophilic component.

54. (~~Withdrawn~~ Original) A liposome or lipid complex comprising amphiphilic molecules that comprise a hydrophilic component positioned over at least a portion of the outer surface of said liposome or lipid complex; wherein said hydrophilic component has at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus, wherein said first and second hydrophobic moieties extend into the hydrophobic bilayer of said liposome or lipid complex.

55. (~~Withdrawn~~ Original) The liposome or lipid complex of claim 54, wherein said amphiphilic molecules comprise a plurality of hydrophobic moieties that extend into the hydrophobic bilayer of said liposome or lipid complex and wherein said hydrophilic component is positioned over a substantial portion of the outer surface of said liposome or lipid complex.

56. (~~Original~~ Currently Amended) The method of claim 57, wherein said amphiphilic molecules are ~~prehydrated amphiphilic molecules~~ in a prehydrated state.

57. (Currently Amended) A method of making a liposome or lipid complex comprising admixing, an aqueous solution or phase, a population of lipid components with a population of amphiphilic molecules, the said amphiphilic molecules being taken as such or in a prehydrated state; wherein said amphiphilic molecules comprise a hydrophilic component having at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus; and optionally ~~a selected chemical or biological agent or cell~~ a selected agent comprising a chemical agent or a biological agent or a biological cell; and wherein said admixing is effective to form said liposome or lipid complex, to encapsulate or trap the said selected agent if provided.

58. (Currently Amended) The method of claim 57 further comprising:
(a) ~~providing a liposome, lipid complex or biological cell; and~~
(b) ~~contacting said liposome, lipid complex or biological cell with an amphiphilic material that comprises~~ contacting or admixing, in an excess of an aqueous solution or phase, a liposome or lipid complex or biological cell, with an amphiphilic material comprising a population of amphiphilic molecules, preferably prehydrated amphiphilic molecules, that comprises a hydrophilic component having at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus; ~~wherein~~ whereupon said first and second hydrophobic moieties extend into the hydrophobic bilayer of said liposome, lipid complex or ~~cell~~ biological cell and ~~wherein~~ said hydrophilic component is positioned over at least a portion of the surface of said liposome, lipid complex or ~~cell~~ biological cell; thereby forming an amphiphilic material-coated liposome, lipid complex or biological cell.

59. (Original) The method of claim 58, wherein said biological cell is a red blood cell.

60. (Original) The method of claim 59, wherein said biological cell is a human red blood cell.

61. (Original) The method of claim 57, further comprising admixing said liposome or lipid complex with a selected agent, wherein said admixing is effective to cause encapsulation or entrapment of said selected agent in said liposome or lipid complex.

62. (~~Withdrawn~~ Original) A kit comprising, in a suitable container, amphiphilic molecules comprising a hydrophilic component having at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus; or a liposomal formulation comprising said amphiphilic molecule.

63. (Currently Amended) The method of claim 61, wherein said selected agent is a blood cell blood product or substitute thereof.

Claims 64 and 65 cancelled

66. (Original) The method of claim 61, wherein said selected agent is an immunological component.

67. (Original) The method of claim 61, wherein said selected agent is a nutrient or a nutritional supplement.

68. (Original) The method of claim 63, wherein said selected agent is an oxygen carrier, haemoglobin or a coagulant.

69. (Original) The method of claim 66, wherein said selected agent is an antigen, an antibody, a cytokine or an anti-inflammatory agent.

70. (Original) The method of claim 61, wherein said selected agent is a chemotherapeutic agent or cytotoxin.

71. (Original) The method of claim 61, wherein said selected agent is a protein, peptide, enzyme, hormone, growth factor or neurotransmitter.
72. (Original) The method of claim 61, wherein said selected agent is an antibiotic, an anti-viral or a fungicide.
73. (Original) The method of claim 61, wherein said selected agent is an anesthetic or a surfactant.
74. (Original) The method of claim 61, wherein said selected agent is nucleic acid molecules, a nucleic acid construct or vector, an antisense nucleic acid or a ribozyme.
75. (Original) The method of claim 61, wherein said selected agent is an agent from Table 3A, Table 3B or Table 4.
76. (Original) The method of claim 61, wherein said selected agent is a pheromone or an agricultural agent.
77. (Original) The method of claim 57, wherein said hydrophilic component of said amphiphilic molecules is a substantially linear, a branched, a pendant or a star hydrophilic component.
78. (Original) The method of claim 57, wherein said hydrophilic component of said amphiphilic molecules is a hydrophilic component from Table 1.
79. (Original) The method of claim 57, wherein at least one of said hydrophobic moieties of said amphiphilic molecules is a hydrophobic moiety from Table 2.
80. (Original) The method of claim 79, wherein at least one of said hydrophobic moieties of said amphiphilic molecules is a deoxy-amino, deoxy-N-methylamino, deoxy-N,N dimethylamino, deoxy-N,N-dimethyl-N-alkylammonium or deoxy-N,N,N

trialkylammonium analogue of a glyceride, wherein said glyceride is a glycerol fattyacid ester/ether, a monoglyceride (mono-fattyacylglycerol), monoalkylglycerol, diglyceride (difattyacylglycerol) or monoalkyl-monofattyacylglycerol.

81. (Original) The method of claim 57, wherein said amphiphilic molecules are bipodal amphiphilic molecules comprising a substantially linear hydrophilic component that has a first and second terminus, and wherein a first and second hydrophobic moiety are separately attached at, or substantially at, said first and second terminus.

82. (Original) The method of claim 57, wherein said amphiphilic molecules are oligopodal or polypodal amphiphilic molecules comprising a branched or star hydrophilic component that has a plurality of termini and a plurality of hydrophobic moieties separately attached to each terminus or proximal thereto.

83. (Original) The method of claim 82, wherein said amphiphilic molecules comprise a plurality of hydrophobic moieties that extend into the hydrophobic bilayer of said liposome or lipid complex and wherein said hydrophilic component is positioned over a substantial portion of the outer surface of said liposome or lipid complex.

84. (Original) The method of claim 57, wherein said liposome or lipid complex comprises between 1% and 99% of said amphiphilic molecules.

85. (Original) The method of claim 57, wherein said liposome or lipid complex comprises about 100% of said amphiphilic molecules.

86. (Original) The method of claim 57, wherein said amphiphilic molecules are non-ionic species.

87. (Original) The method of claim 57, wherein said amphiphilic molecules are charge neutral zwitterionic species.

88. (Original) The method of claim 57, wherein said amphiphilic molecules are (poly)anionic species.
89. (Original) The method of claim 57, wherein said amphiphilic molecules are (poly)cationic species.
90. (Original) The method of claim 57, wherein said amphiphilic molecules comprise branching points or functional groups.
91. (Original) The method of claim 90, wherein said branching points or functional groups are provided by glycerol, pentaerythritol, polyols, hydroxy, amino acids or peptides.
92. (Original) The method of claim 90, wherein said branching points or functional groups are attached to lipid residues.
93. (Original) The method of claim 92, wherein said branching points or functional groups are attached to said lipid residues via linkers or spacer residues.
94. (Original) The method of claim 90, wherein said branching points or functional groups are attached to antigens, antibodies or pendant ligands.
95. (Original) The method of claim 94, wherein said branching points or functional groups are attached to fluorescent, spin, biotin or thio-gold labels or to chelators.
96. (Original) The method of claim 94, wherein said branching points or functional groups are attached to antigens, antibodies or pendant ligands via linkers or spacer residues.

97. (Currently Amended) A method of claim 57 further comprising:

- (a) providing a population of liposomes or lipid complexes that comprise amphiphilic molecules that comprise a hydrophilic component positioned over at least a portion of the outer surface of the liposome or lipid complex; wherein said hydrophilic component has at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus, wherein said first and second hydrophobic moieties extend into the hydrophobic bilayer of the liposome or lipid complex; and
- (b) ~~admixing said selected agent~~ admixing a selected agent comprising a chemical agent or a biological agent or a biological cell with said population of liposomes or lipid complexes, wherein said admixing is effective to cause encapsulation or entrapment of said selected agent in said liposome or lipid complex.

98. (~~New~~Original) A liquid-crystalline multimolecular aggregate comprising a plurality of amphiphilic molecules dispersed in an aqueous solution, said amphiphilic molecules comprising a hydrophilic component having at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus of said hydrophilic component, prepared by the method of claim 57.

99. (~~New~~Original) A liposome or lipid complex comprising amphiphilic molecules that comprise a hydrophilic component positioned over at least a portion of the outer surface of said liposome or lipid complex; wherein said hydrophilic component has at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus, wherein said first and second hydrophobic moieties extend into the hydrophobic bilayer of said liposome or lipid complex, prepared by the method of claim 57.

100. (~~New~~Original) A kit comprising, in a suitable container, amphiphilic molecules comprising a hydrophilic component having at least a first and second terminus and at least a first and second hydrophobic moiety separately attached to, or proximal to, said first and second terminus; or a liposomal formulation comprising said amphiphilic molecule prepared by the method of claim 57.

Status of the Claims, Support for the Claims

The summary status of the claims as per the OA under reference mailed 06/07/2007 is as follows: The previous election requirement is withdrawn, all claims 53-63 and 66-100 are included in the prosecution and examined. Claims 56-61 and 66-100 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention; in addition, the OA rejects claims 53-55, 62 and 98-100 on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1-57 of US Patent No. 6,284,267 and claims 1-45 of US 6,699,499.

The present amendment presents all claims in the case, claims 53-63 and 66-100, in condition for allowance; it amends claims 56-58 and 97 to present these in an even clearer language than before essentially by adapting the Examiner's suggestions, and thereby brings these and all remaining claims which depend from claim 57 and were rejected under 35 U.S.C. 112, second paragraph, in condition for allowance. The amendment also presents separate persuasive arguments against rejection of claims 75 and 78-79, and claims 53-55, 62 and 98-100, and files a Terminal Disclaimer to overcome rejections on the ground of non-statutory obviousness-type double patenting. Salient amendments are:

In claim 56, the phrase 'prehydrated amphiphilic molecules' has been deleted and the phrase 'in a prehydrated state' substituted therefore. In claim 57 line 3, the phrase ', the said amphiphilic molecules being taken as such or in a prehydrated state' has been added; in addition, in line 6, the phrase 'a selected chemical or biological agent or cell' has been deleted and the phrase 'a selected agent comprising a chemical agent or a biological agent or a biological cell' has been substituted therefor. Claim 58 has been restructured; the allegedly confusing phrase '(a) providing a liposome, lipid complex or biological cell; and' has been deleted. In Claim 97 part (b) line 1, the phrase 'said selected agent' has been deleted and the phrase 'a selected agent comprising a chemical agent or a biological agent or a biological cell' substituted therefor. Claims 58 and 97 then are further amended to conform to the currently amended parent claim 57.

Support for each amended claims is available throughout the specification and also is provided in the REMARKS section of this response.